ORIGINAL

SEALED

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

United States of America *ex rel.* Gregory A. Morrissey, Plaintiff, vs. McKesson Corp., Northstar Rx LLC, and Health Mart Systems, Inc. Defendants	Civil Action No. 3:17-CV-03190-X **AMENDED COMPLAINT FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730** **JURY TRIAL DEMANDED**

FILED UNDER SEAL

PLAINTIFF'S COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§3729 *ET SEQ.*

The *qui tam* Relator, Gregory A. Morrissey ("Relator"), on behalf of the United States of America, brings this action against McKesson Corp. and its wholly-owned subsidiaries, Northstar Rx LLC and Health Mart Systems, Inc., (collectively "McKesson" or "Defendants") for violations of the False Claims Act, 31 U.S.C. §§3729-3733, to recover all damages, civil penalties, and all other recoveries provided under the False Claims Act.

SUMMARY OF THE ACTION

1. As a means of controlling the cost of delivering healthcare to those insured by federal healthcare programs and ensuring that federal healthcare procurement is consonant with U.S. trade policy, various federal agencies have imposed explicit requirements on those who

choose to seek reimbursement for pharmaceutical products that are either purchased directly by an agency or are paid for on behalf of an individual insured by a federal healthcare program. These requirements include the truthful, accurate reporting of statutorily defined pricing data and certification that the pharmaceuticals procured with federal money are in compliance with the Trade Agreements Act.

2. Any company who seeks reimbursement from a federal agency for the sale of such pharmaceuticals must adhere to these requirements. Failure to do so renders a claim for such reimbursement false under the False Claims Act.

3. For years, McKesson has knowingly violated these very requirements. The company has falsely reported pricing of the drugs for which it has sought reimbursement. McKesson did not accurately account for discounts, rebates, and other price concessions when calculating the statutorily-defined average manufacturer price ("AMP") and best price ("Best Price") of generic and name-brand drugs. McKesson's false reporting resulted in federal healthcare programs paying far greater prices for the implicated drugs than they would have had McKesson correctly reported pricing.

4. And McKesson has sold to federal agencies—the Veterans' Administration and the Department of Defense—drugs that the company knew were made in countries that were not approved as countries of origin (including China and India) under the Trade Agreements Act. In order to obtain reimbursement payments for those drugs, McKesson falsely certified that the product was TAA compliant. As McKesson knew when it made those false statements, but for those false certifications, the claims would not have been eligible for reimbursement as TAA compliance is a condition of payment.

THE PARTIES

5. The United States is a plaintiff to this action. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Resources and Services Administration ("HRSA"), the Centers for Medicare and Medicaid Services ("CMS"), the United States Department of Veterans Affairs ("VA"), the Veterans Health Administration, and the United States Department of Defense ("DOD") were agencies and instrumentalities of the United States and their activities, operations, and contracts in administering the Medicaid, Veterans Health, and TRICARE Programs were paid from United States funds.

6. Defendant McKesson Corp. is a corporation organized under the laws of Delaware and headquartered in San Francisco, California. U.S. Pharmaceutical Distribution is a business unit within McKesson Corp. At all times material to this action, McKesson Corp. has transacted business in the Northern District of Texas by, including but not limited to, selling and distributing its drugs, including those identified in this Complaint, to purchasers within the Northern District of Texas.

7. Defendant Northstar Rx LLC ("Northstar") is a wholly-owned subsidiary of McKesson Corp. It is organized under the laws of Delaware and has a principal place of business in San Francisco, California. Northstar is a manufacturer of "high quality generic pharmaceuticals." At all times material to this action, Northstar transacted business in the Northern District of Texas by, including but not limited to, selling and distributing drugs under its own labeler code to purchasers within the Northern District of Texas.[1]

8. Defendant Health Mart Systems, Inc. ("Health Mart") is a wholly-owned subsidiary of McKesson Corp. It is organized under the laws of Delaware and has a principal place of business in San Francisco, California. Health Mart franchises thousands of independent pharmacies across the United States. At all times material to this action, Health Mart transacted

[1] Northstar Rx LLC's labeler code is 16714.

business in the Northern District of Texas by, including but not limited to, selling and distributing drugs, including those identified in this Complaint, to purchasers within the Northern District of Texas.

9. Defendant McKesson sells generic, private label pharmaceuticals into the U.S. health care system under various brand names, including Health Mart and Sunmark Private Brand, but using labeling codes registered with the Food and Drug Administration to McKesson Corporation.[2] At all times material to this action, McKesson sold products under the Health Mart or Sunmark brands in the Northern District of Texas.

10. Relator Gregory A. Morrissey is a citizen of the United States and a resident of the State of Texas. Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(l). Mr. Morrissey brings this action on behalf of the United States for violations of the False Claims Act.

11. Mr. Morrissey received his undergraduate degree from the Thomas Edison State University, a Certificate in Government Contract Management from Villanova University, and a Masters of Business Administration from the University of North Carolina at Chapel Hill Kenan-Flagler Business School. From October 2013 through August 2017, Relator was employed by McKesson as a Senior Government Contract Manager for Contract Compliance. In this position, he managed large contracts pertaining to the pricing and sale of pharmaceuticals to the United States pursuant to contracts with the DOD TRICARE System, the Veterans Health Administration, and the Health Resources and Services Administration. In the course of his employment, Relator had direct communications with key decision makers concerning prices charged to the United States. Such communications have made him privy to various marketing methods utilized by McKesson. Through his employment at McKesson, Relator uncovered the False Claims Act violations detailed herein, and is the original source for all such information.

[2] The relevant labeler codes are 62011 (Health Mart) and 49348 (SunMark).

JURISDICTION AND VENUE

12. Jurisdiction is founded upon the False Claims Act (the "Act"), 31 U.S.C. §3729 *et seq*., specifically 31 U.S.C. §3732(a) and (b), and also 28 U.S.C. §§1331, 1345, and is not barred by §3730(e). The information upon which these allegations are based was voluntarily provided by Relator to the Federal Government prior to filing this Complaint pursuant to 31 U.S.C. §§3730(e)(4)(B) and 3730(b)(2). No public disclosure of the allegations or transactions on which this action is based occurred before the filing of the initial complaint in this matter, and this action is not based upon a public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or General Accounting Office report hearing, audit, or investigation, or from the news media. In the alternative, should the court find that there was a public disclosure of such allegations or transactions before the filing of this action, and that this action is based on a public disclosure of such allegations or transactions, then Relator is the original source of the information on which any such publicly disclosed allegations or transactions are based, has direct, independent knowledge of such information, and voluntarily provided the information to the Government before filing this action.

13. Venue in the Northern District of Texas is appropriate under 31 U.S.C. §3732(a) and sufficient contacts exist for jurisdiction in that Defendants conduct business and sell pharmaceuticals, including those identified in this Complaint, in the Northern District of Texas. Such drugs, as Defendants know, (a) have been and continue to be supplied to federal health care program recipients, including Medicaid, VA, and TRICARE recipients; and (b) have been and continue to be the subject of claims for reimbursement made by federal health care program drug providers, including hospitals and pharmacies.

14. A copy of the initial Complaint in this matter and written disclosures of substantially all material evidence and information Relator possesses was served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure, prior to the filing of the initial Complaint *in camera* and under seal by delivering a copy of the initial Complaint, material evidence, and information to the United States Attorney for the Northern District of

Texas and by sending a copy of the initial Complaint, material evidence, and information by certified mail to the Attorney General of the United States in Washington, District of Columbia.

BACKGROUND REGARDING THE RELEVANT FEDERAL HEALTH CARE PROGRAMS

A. *Medicaid*

15. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Enacted in 1965, the Medicaid Program functions as a jointly-funded cooperative undertaking between the Federal and State Governments. Each State administers its own Medicaid program, but the State's programs are governed by Federal statutes, regulations, and guidelines.

16. The Medicaid Program pays for services pursuant to plans developed by the states and approved by HHS Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily-established share of "the total amount expended . . . as medical assistance under the State plan . . . " *See* 42 U.S.C. § 1396b(a)(1). This federal-to-state payment is known as federal financial participation.

17. Benefits for drugs are optional but all States have opted to provide Medicaid drug reimbursement coverage.

18. After hearings in 1989, Congress concluded that the Federal government was paying significantly more for drugs under State Medicaid Programs than certain private payors. *See, e.g.,* Skyrocketing Drug Prices: Hearings before the Special Committee on Aging, United States Senate, 101st Congress, 290-297 (1989).

19. Congress addressed this inequity in 1990 by establishing the Medicaid Drug Rebate Program. The purpose of the Drug Rebate Program was to ensure that the Medicaid program received the "benefit of the best price for which a manufacturer sells a prescription drug

to any public or private purchaser." H.R. Rep. No. 101.881 at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108.

20. To accomplish its goal of containing skyrocketing drug costs, Congress required that for a manufacturer's drug to be reimbursed by Medicaid, the manufacturer must enter into a Rebate Agreement with the HHS Secretary, via CMS.

21. Under the program, manufacturers of covered drugs are required to report their "Average Manufacturer Price" ("AMP") for both generic and branded drugs, and "Best Price" for each branded drug to CMS through the Drug Data Reporting for Medicaid system on a quarterly basis. Under the Rebate Program, Best Price is calculated based on "lowest price available from the manufacturer . . . to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity" and includes cash discounts, free goods, volume discounts and rebates. 42 U.S.C. § 1396r-8(c)(1)(C). Pursuant to 42 U.S.C. § 1396r-8(k)(l), AMP is interpreted to mean, "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts."

22. CMS, in turn, uses the AMP and Best Price to calculate a rebate amount for each covered drug, with the precise formula differing depending on whether the drug is single-sourced or multi-sourced. The AMP is also used to calculate the Federal Upper Limit for certain generic drugs. The Federal Upper Limit limits government reimbursement for generic drugs with at least three equivalents to no more than 175% of a weighted AMP basket average. 19 U.S.C. § 1927(e)(5). The Federal Upper Limit is factored in by some states to determine the price paid for drugs.

23. Bundled sales, including those at issue in this action, are sales in which the condition for a rebate or discount to be given is that two or more drugs are purchased together, or in which the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately. Bundled sales are a common industry practice among drug manufacturers.

24. Pursuant to Medicaid regulations and the terms of the Rebate Agreement entered into between Defendants and CMS, for Best Price and AMP calculations in the context of bundled sales, the discount must be allocated proportionally to the dollar value of the units of each drug sold under the bundled agreement.

25. With respect to single-source or innovator multiple-source drugs (also called NDA drugs, based on the relevant FDA approval system, or branded drugs), each manufacturer agrees to pay the state Medicaid program a quarterly rebate to ensure that all sales meet the Best-Price criteria. 42 U.S.C. § 1396 *et seq.*

26. Under the Rebate Program, § 1396r-8(c)(l)(A) and (B), over each three-month reporting period, the provider must rebate the state Medicaid program according to a "Unit Rebate Amount" formula put forth by CMS. That formula includes the total rebate to equal the sum of a basic rebate calculation and an inflation-based additional rebate calculation.

27. The basic rebate for branded drugs is defined as an amount equal to the product of:

a. the total number of units sold to the State Medicaid drug program, for each dosage form and strength (as reported by the State); and

b. the greater of:

i. the difference between the AMP minus the manufacturer's Best Price for the dosage form and strength of the drug; or

ii. the minimum rebate percentage of the AMP, which is 23.1%.

28. At the second step in the process, the amount which a single dose of a drug exceeds the AMP adjusted for the consumer price index—urban ("CPI-U"), as calculated by the Bureau of Labor Statistics, is multiplied by the total units sold in that quarter to create an additional rebate obligation. 42 § 1396r-8(c)(2)(A).

29. Based on the quarterly representations of each drug provider, CMS calculates the rebate amount as either AMP minus Best Price or the 23.1 % minimum, adjusted for price increases exceeding inflation. CMS then forwards the figures by National Drug Code (the

identification number for each dosage and unit size for each drug) to each State. Each State then multiplies the rebate amount by the number of units that the State paid for during the quarter for each NDC number to determine the total rebate amount due and submits this amount to the manufacturer for payment. The manufacturer remits this payment on a quarterly basis.

30. The amount received by a State in Medicaid rebates is considered a reduction in the total amount expended under any given State's plan. Therefore, the less any given State receives in Medicaid rebates, the greater the total amount expended by the State and the more the federal government must correspondingly pay to each State, because the Federal Government contributes a set percentage of the total amount each State expends on Medicaid. 42 U.S.C. § 1396b(a)(l); 42 U.S.C. § 1396r-8(b)(l)(B).

31. With respect to generic or ANDA drugs (formally referred to as multiple source drugs), the manufacturer is not required to report the Best Price to CMS, only the AMP. The Rebate Program requires manufacturers to pay a Unit Rebate Amount on multiple-source drugs equal to 13% of the AMP.[3]

32. Whenever a manufacturer fails to make a rebate payment in a timely manner, the manufacturer's outstanding debt accrues daily interest at a rate determined by the yield rate of 13-week Treasury bills.[4]

B. *340B Drug Pricing Program*

33. In addition, as a condition of participating in Medicaid, all drug manufacturers are required to participate in the 340B Drug Pricing Program ("340B Program"), enacted as part of the Public Health Service Act of 1944 and codified at 42 U.S.C. § 256b. The Health Resources and Services Administration administers the 340B Program.

34. The 340B Program creates a price ceiling for certain covered entities listed in the statute, 42 U.S.C. § 256b(a)(4), and requires manufacturers to offer those entities prices at or below the applicable price ceiling.

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[3] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html
[4] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html

35. The ceiling price is set by the statute as the AMP, reduced by a certain rebate percentage. That rebate percentage is calculated quarterly, and is defined as the Unit Rebate Amount as calculated under, 42 U.S.C. § 1396r-8(c), divided by the average manufacturer price for the drug. 42 U.S.C. § 256b(a)(2)(A). This rebate must also be provided for purchases of over-the-counter drugs, as if they were covered by 42 U.S.C. § 1396r-8(c). 42 U.S.C. § 256b(a)(2)(B). As with Medicaid, the Unit Rebate Amount increases if the AMP rises at a rate higher than inflation, as measured using the CPI-U.

36. Historically, because of the basic rebate and the inflation factor, the calculation could result in negative 340B prices. Effective January 1, 2010, however, for 340B purposes the Unit Rebate Amount is capped at 100% of AMP. However, CMS recognizes that it is not reasonable to set a 340B ceiling price at zero. In those cases, policy guidance instructs manufacturers to charge $0.01 per unit for each drug, called "penny pricing."

37. In total, entities covered by the 340B program account for roughly 5% of all pharmaceutical purchases nationwide.

C. ***Drug Data Reporting System for Medicaid***

38. Manufacturers who enter into a rebate agreement under 42 U.S.C. § 1396r-8(a) are required to submit pricing information through the Drug Data Reporting system. Data must be submitted by individual NDCs. 42 U.S.C. § 1396r-8(b)(3)(A)(iii).

39. National Drug Codes are unique, three-segment numbers established under the Drug Listing Act of 1972 and are used by the Food and Drug Administration ("FDA") as a universal product identifier. 21 C.F.R. § 207.33.

40. A NDC is ten to eleven digits long. The basic structure includes the labeler code (manufacturer), the product code (drug), and package code (dose). 21 C.F.R. § 207.33(b)(i-iii). The labeler code is assigned by the FDA.

41. The Medicaid Drug Rebate program requires that any drug for which reimbursement will be sought from the Medicaid program be listed in the Drug Data Reporting

system. Generally, a manufacturer is required to provide a rebate if any of its NDC's are purchased by a Medicaid program in a given quarter.

42. Manufacturers must terminate their products in the Drug Data Reporting system when they decide to withdraw an NDC from market. The manufacturer of a terminated product is required to submit pricing information to the Drug Data Reporting system for four quarters beyond the submitted termination date quarter. A manufacturer must pay the last rebate amount calculated for any Medicaid sales after a product's termination date.

43. CMS, in a September 2014 notice, reminded manufacturers that the termination date for products in the Drug Data Reporting system and subject to a Medicaid rebate must be submitted in a timely manner or be subject to civil monetary penalties under 42 U.S.C. § 1927(b)(3)(C)(ii).

44. Only after five years have passed after the date an NDC is terminated in the Drug Data Reporting system may the manufacturer designate it within the system for a different product.

D. *Veterans Health Administration Prime Pharmaceutical Vendor Program*

45. The Department of Veterans Affairs has delegated authority from the Government Services Administration to award federal supply contracts for pharmaceuticals and medical supplies. These contracts, collectively known as the VA Federal Supply Schedule, are made directly with manufacturers and intended to meet the healthcare needs of the VA and much of the federal government except the DOD and CMS programs.

46. The Veterans Health Care Act requires manufacturers to make covered drugs available for Federal Supply Schedule contracting as a condition of Medicaid payment. 38 U.S.C. § 8126. Typically, drugs on the Federal Supply Schedule are branded or branded-generics.

47. By law, all Federal Supply Schedule contracts that exceed a specified value are subject to the Trade Agreement Act ("TAA"), which requires goods and services purchased by

the government to be sourced from the United States, countries that have signed specified multilateral trade agreements, or statutorily-designated countries. 19 U.S.C. § 2501.

48. The United States Trade Representative, under delegated authority from the President of the United States, determines biannually the transaction threshold at which TAA requirements apply to government contracts. The current threshold is $198,000. 80 Fed. Reg. 77694 (Dec. 15, 2015).

49. Federal Supply Schedule contracts have no specified value because they are subject to rolling orders over time, and are more formally known as indefinite delivery, indefinite quantity ("IDIQ") contracts. Because Federal Supply Schedule contracts are IDIQ, their solicitations are standing and a projected value is used to determine TAA applicability.

50. Prior to April 2016, VA was not permitted to waive TAA requirements in purchases it made, even for a drug that was not available in the domestic market. That authority rested solely with GSA. In April 2016, the VA carved out an authority for contracting officers to issue TAA waivers for a sub-class of branded and biologic drugs.

51. On April 15, 2017, the VA enacted a *de facto* waiver of TAA requirements by requiring all covered drugs (branded or branded-generic) to be on a Federal Supply Schedule. Up until that time, subject to the individual determination process established in April 2016, there was an unequivocal requirement that Federal Supply Schedule drugs be TAA complaint.

52. Pharmaceutical purchases made pursuant to a Federal Supply Schedule can be made directly by a government agency from the contracting manufacturer. However, the VA has established a Prime Pharmaceutical Vendor program to act as a centralized, just-in-time distributor for the system. Typically, agencies can purchase Federal Supply Schedule drugs, non-Federal Supply Schedule drugs, and generic drugs through the Prime Pharmaceutical Vendor.

53. Under the current Prime Pharmaceutical Vendor, agencies may purchase generic drugs through a process called "open market" purchasing. The Prime Pharmaceutical Vendor contract procedurally requires that non-contracted generics meeting specific criteria be made

available under the Prime Pharmaceutical Vendor Contract. All other items not on contract are purchased on the open market with government purchase cards.

54. Open market purchases are made pursuant Wholesale Acquisition Cost Based Priced Generics criteria ("WBPG") as detailed in the Prime Pharmaceutical Vendor Contract. A WBPG drug is any non- Federal Supply Schedule drug that meets five criteria: (1) it is generic; (2) it is FDA approved; (3) it has a published WAC price; (4) it has an FDA approved NDC; and (5) it is TAA compliant.

55. The holder of the Prime Pharmaceutical Vendor contract is required to certify its compliance with the TAA provisions applied under the Federal Acquisitions Regulation ("FAR") 52.225-5.

E. *Department of Defense National Prime Vendor Program*

56. In 1967, the DOD created the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), which is a federally funded medical program created by Congress. 10 U.S.C. § 1071. CHAMPUS beneficiaries include active military personnel, retired personnel, and dependents of both active and retired personnel. *Id.*

57. In 1995, the Department of Defense established TRICARE, a managed health care program, which operates as a supplement to CHAMPUS. *See* 32 C.F.R. §§ 199.4, 199.17(a). Since the establishment of TRICARE in 1995, both programs are frequently referred to collectively as "TRICARE." The purpose of the TRICARE program is to improve healthcare services to beneficiaries by creating "managed care support contracts that include special arrangements with civilian sector health care providers." 32 C.F.R. § 199.17(a)(1). The TRICARE Management Activity ("TMA") oversees this program.

58. In order to provide pharmaceuticals to CHAMPUS beneficiaries worldwide, the DOD in 1993 first created a prime vendor program, a centralized wholesale distributor managed by the Defense Logistics Agency ("DLA"). The prime vendor delivers product at either its acquisition cost or at a price agreed to in advance with DLA.

59. Today, DLA utilizes the National Prime Vendor program to distribute construction material, equipment, clothing, textiles, and related services pursuant to terms specified by the contract award.

60. DLA traditionally purchases products—such as pharmaceuticals—through the National Prime Vendor pursuant to Distribution and Pricing Agreements ("DAPA"), contracts between the DLA and supplier that sets the DOD's acquisition price. The DOD has the option to purchase drugs directly from a manufacturer pursuant to other federal pricing agreements, but the manufacturer must pay a chargeback to the National Prime Vendor equal to any amount the purchase price exceeds the DAPA price.

61. In 1999, the VA and DOD signed a Memorandum of Understanding that resulted in DAPA contracting being deemphasized in favor of the DOD using the VA's Federal Supply Schedule contracts, an agreement that still stands.

62. The Defense Federal Acquisition Regulation ("DFARS") obligates a National Prime Vendor to adhere to the Trade Agreements Act. In order for a TAA non-compliant product to be approved for purchase, the National Prime Vendor must request a Domestic Non-Availability Determination ("DNAD") *through* the attendant contracting officer. 48 C.F.R. § 225.7002-2(b). The contracting officer then must seek the DNAD from the Under Secretary of Defense for Acquisition, Technology, & Logistics—the authority is non-delegable.

63. A DNAD is only appropriate if the National Prime Vendor cannot acquire the necessary quality or quantity of a product domestically. A product that is otherwise unavailable domestically but has not received a DNAD is nonetheless TAA non-compliant.

MCKESSON'S SUBMISSION OF FALSE CLAIMS FOR PAYMENT TO THE UNITED STATES

A. *Systematic Misreporting of AMP and Best Price to CMS*

64. Beginning in October 2013, McKesson failed to properly report AMP and Best Price to CMS, as required by 42 U.S.C. § 1396r-8. As a result, the Medicaid Program paid a larger net amount than it would have had McKesson accurately reported pricing.

65. McKesson outsourced its AMP and Best Price calculations to a third party—Lincoln Consulting—but failed to provide the appropriate oversight to ensure those calculations were accurate. They were not accurate, because McKesson intentionally omitted critical pricing inputs.

66. As the manufacturer, it was McKesson's obligation to certify the truth and accuracy of the pricing information it submitted to the Drug Data Reporting system. McKesson failed to implement a formal process to ensure that the certifications it provided were truthful and accurate—staff received no training on this process or what the federal government required of those submitting certifications.

67. McKesson's procedures resulted in material omissions from its AMP calculations, which, in turn, resulted in incorrect rebate payments that McKesson was required to make to the federal government and a higher net price paid by federal and state programs.

68. Both CMS and HRSA have told McKesson that its reporting did not comply with the law.

69. On August 26, 2016, Relator received an email from Krista M. Pedley, the Director of the HRSA Office of Pharmacy Affairs, informing him that McKesson had been identified as providing "incorrect information in regards to your 340B database."

70. On October 27, 2016, the National Technical Director at CMS called Relator to state that McKesson's practices were "significantly out of compliance" with its obligations to CMS.

71. McKesson's concerns about its price reporting deficiencies extended beyond its private label brands. The same falsities have infected McKesson's reporting for drugs sold under the Northstar brand, as well.

72. Because of McKesson's mispricing of drugs over the last ten years, States have paid a higher net price for necessary medications, even when factoring in rebates, requiring the federal government to pay higher reimbursements to the State Medicaid programs. The

consequences of McKesson's actions are amplified by inflating both the Federal Upper Limit, the maximum price the government pays for certain drugs, and the 340B program's prices.

73. The total federal money implicated by McKesson's failure to properly price drugs according to Medicaid requirements is staggering. From the first quarter of 2015 through the second quarter of 2016, the combined Medicaid purchases of McKesson private label products alone amounted to $13,469,779.50. And those six quarters represent only a fraction of the public money tainted by McKesson's false statements.

B. ***Reporting Single-Source Drugs as Multi-Source***

74. McKesson also illegally reduced its required rebate payments to the government by wrongfully misclassifying NDA drugs as ANDA (generic) drugs, and reporting only the AMP price, rather than also including the Best Price.

75. This wrongful misclassification allowed McKesson to rebate the Medicaid program at only 13% of AMP, rather than the higher 23.1% minimum reimbursement rate for single-source drugs.

76. During the October 27, 2016 call from the National Technical Director of CMS to Relator, the Director made clear that CMS both knew about the mistakes, and had extreme concerns with the practice.

C. ***McKesson's Improper Recycling of Withdrawn National Drug Codes and False Reporting of Drug Data Reporting System Termination Dates***

77. McKesson further manipulated the prices it reported by improperly recycling NDCs for its products.

78. The law is clear. Manufacturers cannot recycle an NDC until at least five years have passed from the date that NDC was terminated in the Drug Data Reporting system. Yet McKesson paid this requirement no heed, routinely re-appropriating NDCs for drugs that either were not yet terminated or for which the five-year window had not expired. The results were absurd—stool softeners were submitted as expectorant, antacids as children's multivitamins—

and rendered the company's price reporting and rebate payments inaccurate for the affected drugs.

79. Moreover, even where McKesson has used NDCs correctly, it has avoided some of its obligations to provide rebates to the Medicaid program by reporting products as terminated to the Drug Data Reporting system before removing them from the market. In October 2016, Relator received an inquiry from the CMS Medicaid Drug Rebate Operations team regarding price submissions for NDCs that did not match the associated product. As McKesson brought new products to market, it recycled the NDCs for products it had discontinued.

80. A product's early termination from the Drug Data Reporting system deprives the government of an accurate basis for calculating any rebates owed after the date. Even assuming a product is terminated only a quarter early, rebates and Federal Upper Limit would be adversely affected. Relator has identified products that McKesson terminated over a year early.

81. Relator also discovered that McKesson had terminated some products that it never withdrew from market. Other products were never terminated in the Drug Data Reporting system, but were discontinued internally by McKesson.

82. McKesson's willfully non-compliant approach to termination of NDCs is yet another example of the company's knowing and unjustifiable false reporting of drug pricing—conduct that has left the taxpayer holding the bag.

D. *False Certifications of TAA Compliance under the Prime Pharmaceutical Vendor Contract*

83. In May 2012, McKesson contracted with VA to be the Prime Pharmaceutical Vendor to VA and Other Government Agencies (OGAs), including the Bureau of Prisons and the Indian Health Service. This contract (hereinafter, the "Prime Pharmaceutical Vendor Contract"), designated VA797P-12-D-001, is publicly available from the U.S. General Services Administration at the Federal Business Opportunities website www.fbo.gov.

84. The Prime Pharmaceutical Vendor Contract went into effect on May 10, 2012, with a "base performance period" running from May 10, 2012 to May 9, 2014. The Contract provides for three, two-year options renewable at VA's discretion.

85. As an express condition of the Prime Pharmaceutical Vendor Contract, McKesson certified that it would comply with the Trade Agreements Act (19 U.S.C. § 2501, *et seq.*, 19 U.S.C. 3301 note). Section 52.212-5(b) of the Prime Pharmaceutical Vendor Contract incorporates by reference and requires McKesson to comply with FAR 52.225-5, Trade Agreements (AUG 2009) (19 U.S.C. 2501, et seq., 19 U.S.C. § 3301 note). FAR 52.225-5(b) provides, in relevant part, that McKesson "shall deliver under this contract only U.S.-made or designated country end products[.]"

86. The value of the Prime Pharmaceutical Vendor Contract, as indicated by the "Total Award Amount" field on its signature page, is $31,623,538,274.00.

87. Under "TYPE OF CONTRACT," the Prime Pharmaceutical Vendor Contract is described as "a hybrid of Requirement Type and IDIQ contracts. Pharmaceutical items that are priced under separate FSS [Federal Supply Schedule] contracts, VA National Contracts, [Blanket Purchase Agreements], and [Basic Ordering Agreements] shall be Indefinite Delivery, Requirements-Type Contract(s) (Refer to FAR Clause 52.216-21, 'Requirements'). Medical/Surgical Products and WBPG Pharmaceuticals shall be IDIQ contracts. (Refer to FAR Clause 52.216-22, 'Indefinite Quantity'). Procurement of Medical/Surgical Products and WBPG Pharmaceuticals is optional."

88. Relator, as manager of the Prime Pharmaceutical Vendor Contract, had direct and specific knowledge of McKesson's failure to comply with the Contract's Trade Agreements Act obligations. McKesson repeatedly and knowingly falsely certified to the VA and OGAs that products delivered pursuant to the Prime Pharmaceutical Vendor Contract originated in the United States or in designated countries, when McKesson was aware that these drugs were made in India or China or other non-designated countries.

89. As a result of its false certifications, McKesson sold pharmaceutical drugs to the United States that violated the Trade Agreements Act. As McKesson knew at the time it submitted claims for reimbursement to federal programs, failure to adhere to TAA requirements precluded such payments.

90. In addition to its misrepresentations as to drugs that it manufactured, McKesson also submitted false claims to federal programs for non-TAA-compliant drugs made by other manufacturers, as well. As required of it, McKesson maintains extensive internal records of all products delivered under the Prime Pharmaceutical Vendor Contract, including each product's supplier, country of origin, and whether that product is compliant or non-compliant with McKesson's obligations under the Prime Pharmaceutical Vendor Contract, the TAA, and FAR 52.225-5.

91. McKesson conducts annual audits of its suppliers and knows that often the source of drugs was a TAA non-compliant country of origin. But McKesson, despite its obligations as the Prime Pharmaceutical Vendor, sourced those drugs and the federal reimbursements without adequately informing the VA or any other purchasing program about the violations.

92. Since entering into the Prime Pharmaceutical Vendor Contract in 2012, McKesson has made hundreds of thousands of non-compliant deliveries to the VA and OGAs. Non-compliant sales by McKesson from 2015 to July 2017 of Indian, Chinese, and other non-designated-country-made pharmaceutical drugs to the United States totaled $603,847,680.22.

93. In the ordinary course, McKesson tracks its non-compliant sales by NDC. Those records indicate that McKesson's non-compliant sales spanned more than one thousand pharmaceutical drugs, hundreds of manufacturers or repackagers, and were made to thousands of different VA and OGA facilities under the Prime Pharmaceutical Vendor Contract.

94. Most of McKesson's non-compliant sales were of drugs manufactured in India. For example, from 2015 to July 2017, McKesson sold approximately $31 million of Colcrys that had been manufactured by AR Scientific in India, a non-designated country, to hundreds of VA Medical Centers, Outpatient Pharmacies and other facilities under the Prime Pharmaceutical

Vendor Contract. None of these sales were made pursuant to any waivers relieving McKesson of its obligations under the TAA or FAR 52.225-5. Similarly, from 2015 to July 2017, McKesson sold approximately $34 million of Lamictal, Malarone, Mepron, and Valtrex manufactured by Glaxosmithkline in India to hundreds of VA Medical Centers, Outpatient Pharmacies and other facilities under the Prime Pharmaceutical Vendor Contract. None of these sales were made pursuant to DNADs or other waivers relieving McKesson of its obligations under the TAA or FAR 52.225-5.

95. Federal programs relied upon McKesson's material and false misrepresentation about the country of origin of these products as a condition of payment. The violations of the TAA and the FAR 52.225-5 rendered the drugs ineligible for reimbursement and all claims submitted for such payments false under the False Claims Act. The contracting officers did not possess the authority to waive any TAA requirements, thus the non-compliant sales could not have been made under the guise of the government's acquiescence.

E. *False Certifications of Trade Agreement Act Compliance under the National Prime Vendor Contract*

96. In December 2012, McKesson contracted with the DOD to become a National Prime Vendor to distribute pharmaceuticals mail-ordered by TRICARE beneficiaries through the current TRICARE Pharmacy contractor, Express Scripts. This contract (hereinafter, the "National Prime Vendor Contract") designated SPM2DX-11-R-0001, is publicly available from the U.S. General Services Administration at the Federal Business Opportunities website www.fbo.gov.

97. The National Prime Vendor Contract contained a base period of 30 months—effective from December 17, 2012, to June 16, 2015—and three, 30-month option periods exercisable at the DLA's discretion. The estimated cumulative value of the National Prime Vendor Contract at the time it was awarded was $14,300,000,000.

98. In addition, the National Prime Vendor Contract was conditioned on the recipient being able to demonstrably meet surge and sustainment requirements—the ability to fulfill

contractual obligations in a time of war. The war readiness requirement added an estimated $3,200,000 to the base contract period and to each option period.

99. As was true for the Prime Pharmaceutical Vendor Contract, by entering into the National Prime Vendor Contract, McKesson certified that it would comply with the Trade Agreements Act. The National Prime Vendor Contract incorporates by reference and requires McKesson to comply with DFARS 252.225-7021, Trade Agreements (Nov. 2012) (48 C.F.R. § 252.225-7021). The regulation under subsection (c) provides in relevant part that McKesson "shall deliver under this contract only U.S.-made or designated country end products[.]"

100. Relator, as manager of the National Prime Vendor Contract, had direct and specific knowledge of McKesson's failure to comply with the National Prime Vendor Contract's Trade Agreements.

101. McKesson has falsely certified to the VA and OGAs that products delivered pursuant to the National Prime Vendor Contract originated in the United States or in designated countries, when McKesson knew they were made in India, China, or other non-designated countries.

102. Because of its false certifications, McKesson sold pharmaceutical drugs to the United States that violated the Trade Agreements Act. As McKesson knew at the time it submitted claims for reimbursement to federal programs, failure to adhere to TAA requirements precluded such payments.

103. In addition to its misrepresentations as to drugs that it manufactured, McKesson also submitted false claims to federal programs for non-TAA-compliant drugs made by other manufacturers, as well. As required of it, McKesson maintains extensive internal records of all products delivered under the National Prime Vendor Contract, including each product's supplier, country of origin, and whether that product is compliant or non-compliant with McKesson's obligations under the National Prime Vendor Contract, the TAA, and FAR 52.225-5.

104. McKesson conducts annual audits of its suppliers and knows that often the source of drugs was a TAA non-compliant country of origin. But McKesson, despite its obligations

under the National Pharmaceutical Vendor contract, sourced those drugs and the federal reimbursements while engaging in woefully insufficient efforts to inform DOD about the violations.

105. McKesson maintains extensive internal records of all products delivered under the National Prime Vendor Contract, including each product's supplier, country of origin, and whether that product is compliant or non-compliant with McKesson's obligations under the National Prime Vendor Contract, the TAA and DFARS 252.225-7021.

106. Since entering into the National Prime Vendor Contract in 2012, McKesson has made hundreds of thousands of non-compliant deliveries to the DOD. Non-compliant sales by McKesson from 2015 to July 2017 of Indian, Chinese, and other non-designated-country-made pharmaceutical drugs to the United States totaled $331,796,323.54.

107. McKesson knew how to request a waiver of TAA requirements but failed to obtain such waivers for the vast majority of non-compliant products. In October 2015, McKesson had obtained a waiver for only 3% (424) of the 12,894 non-compliant drugs it sold to through the National Prime Vendor Contract.

108. In the ordinary course, McKesson tracks its non-compliant sales by NDC. Those records indicate that McKesson's non-compliant sales spanned more than one thousand pharmaceutical drugs and hundreds of manufacturers or repackagers and were made to thousands of different VA, and OGA facilities under the National Prime Vendor Contract.

109. Federal programs relied upon McKesson's material and false misrepresentation about the country of origin of these products as a condition of payment. The violations of the TAA and the DFAR 252.225-7021 rendered the drugs ineligible for reimbursement and all claims submitted for such payments false under the False Claims Act. The contracting officers did not possess the authority to waive any TAA requirements, thus the non-compliant sales could not have been made under the guise of the government's acquiescence.

McKesson Retaliated against Relator for Reporting His Concerns

110. Relator on more than one occasion reported each of the aforementioned legal violations through the appropriate internal channels. The concerns he raised were ignored by upper management. In retaliation for having engaged in this protected conduct, McKesson stripped Relator of his job responsibilities offering merely a pretextual and false justification that he was no longer "a top performer."

VIOLATIONS OF THE FALSE CLAIMS ACT,

31 U.S.C. §§ 3729-3733

COUNT I

FALSE CLAIMS ACT: MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

111. Relator realleges and incorporates by reference paragraphs 1 through 123 as if fully set forth herein and further alleges as follows:

112. From at least November 2007 Defendants knowingly (as defined in §3729(b)) made, used, and caused to be made or used, false records or statements to have false or fraudulent claims paid or approved by the Government, in that Defendants submitted false information to CMS on a quarterly basis, as set forth herein, regarding the Best Price and Average Manufacturer price of drug products it was providing to those agencies. By reporting this false information, McKesson caused Medicaid Programs to overpay for medications and caused corresponding increases in the quarterly calculations of drug reimbursement costs prepared and submitted by each State's Medicaid Program to the federal government pursuant to 42 U.S.C. §1396b (the "Submissions"), which are used by the federal government to calculate the federal funding due each State's Medicaid drug reimbursement program. The Submissions thereby each constitute a false claim which the Government has paid or approved pursuant to the False Claims Act, 31 U.S.C. §3729(a)(2).

113. Neither the federal government nor any state governments had any knowledge that McKesson had provided to CMS the false information that is the subject of this Complaint.

114. Defendant McKesson knew that the information it supplied to CMS was utilized by the United States and the State Governments to determine the required amount of rebate that each drug manufacturer had to pay to each State's Medicaid Program.

115. Defendants' reporting violations have caused the claims for reimbursement for single-source drugs to be false and fraudulent, in violation of 31 U.S.C. § 3729(a)(l) and (2).

116. Because of Defendants' conduct as set forth in this Count, the United States suffered actual damages in violation of 31 U.S.C. § 3729(a)(2).

COUNT II

FALSE CLAIMS ACT: MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

117. Relator realleges and incorporates by reference paragraphs 1 through 123 as if fully set forth herein and further alleges as follows:

118. Defendants, from at least October 2013, and continuing at least until August 2017, knowingly (as defined in §3729(b)) made, used, and caused to be made or used, false records or statements to have false or fraudulent claims paid or approved by the Government, in that Defendants made false statements concerning whether drugs sold under the Medicaid program were properly classified as single- or multi-source, for the purpose of decreasing Defendants' obligations to reimburse the government.

119. Neither the federal government nor any state governments had any knowledge that McKesson had provided to CMS the false information that is the subject of this Complaint.

120. Defendant McKesson knew that the information it supplied to CMS was utilized by the United States and the State Governments to determine the required amount of rebate that each drug manufacturer had to pay to each State's Medicaid Program. Defendants fraudulently inflated the prices for their products and its rebate obligations, therefore causing each State's Submissions to be falsely inflated, resulting in great financial loss to the United States.

121. Defendants' reporting violations have caused the claims for reimbursement for single-source drugs to be false and fraudulent, in violation of 31 U.S.C. § 3729(a)(l) and (2).

122. Because of Defendants' conduct as set forth in this Count, the United States suffered actual damages in violation of 31 U.S.C. § 3729(a)(2).

COUNT III

FALSE CLAIMS ACT: MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO HAVE A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

123. Relator realleges and incorporates by reference paragraphs 1 through 123 as if fully set forth herein and further alleges as follows:

124. Defendants, from at least May 2012, and continuing at least until August 2017, knowingly (as defined in §3729(b)) made, used, and caused to be made or used, false records or statements to have false or fraudulent claims paid or approved by the Government, in that Defendants made false statements concerning whether drugs sold under the Prime Pharmaceutical Vendor Contract were compliant the TAA and FAR 52.225-5.

125. Defendants, from at least December 2012, and continuing at least until August 2017, knowingly (as defined in §3729(b)) made, used, and caused to be made or used, false records or statements to have false or fraudulent claims paid or approved by the Government, in that Defendants made false statements concerning whether drugs sold under the National Prime Vendor Contract were compliant with DFARS 252.225-7021, Trade Agreements (Nov. 2012) (48 C.F.R. 252.225-7021).

126. The federal government did not have any knowledge that McKesson had provided to the VA, DOD, or any OGA the false information that is the subject of this Complaint.

127. Defendants' reporting violations have caused the claims for reimbursement for single-source drugs to be false and fraudulent, in violation of 31 U.S.C. § 3729(a)(l) and (2).

128. Because of Defendants' conduct as set forth in this Count, the United States suffered actual damages in violation of 31 U.S.C. §3729(a)(7).

COUNT IV

FALSE CLAIMS ACT: ANTI-RETALIATION PROVISION

129. Relator realleges and incorporates by reference paragraphs 1 through 128 as if fully set forth herein and further alleges as follows:

130. During the course of his employment, Relator investigated numerous instances where he reasonably believed that Defendants were violating the False Claims Act. Relator made numerous reports to his supervisors and other company officials regarding Defendants' fraudulent conduct and violations of the False Claims Act and he repeatedly attempted to stop that conduct.

131. Defendants were aware that Relator had engaged in activities in furtherance of a potential action under the *qui tam* provisions of the False Claims Act. Defendants were also aware of at least some of Relator's efforts to stop the violations of the False Claims Act.

132. Because Relator was engaging in activities that are protected under the False Claims Act's anti-retaliation provision, 31 U.S.C. § 3730(h), Defendants took adverse employment actions against Relator amounting to a constructive termination of his employment.

133. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment and has suffered additional economic and non-economic damages. Relator is entitled to all relief necessary to make him whole.

REQUEST FOR RELIEF

WHEREFORE Relator, on behalf of the United States, demands that judgment be entered in its favor and against Defendants McKesson Corp., Northstar Rx LLC, and Health Mart Systems, Inc. for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This includes three times the amount of damages to the Federal Government plus civil penalties for each false record or statement made, used, or caused to be made or used and any other recoveries provided for under the False Claims Act.

Further, Relator, on his behalf, requests that he receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that his award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action. In addition, Relator requests that he be awarded double his back-pay losses under 31 U.S.C. § 3730(h), plus front pay, interest, costs, and attorneys' fees and special damages.

DEMAND FOR A JURY TRIAL

A jury trial is demanded in this case.

Dated: December 23, 2020

Respectfully submitted,

s/ Jeffrey S. Gleason

Jeffrey S. Gleason (*pro hac vice application* to be filed)
Jamie R. Kurtz (*pro hac vice application* to be filed)
Geoffrey H. Kozen (*pro hac vice application* to be filed)

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Attorneys for Relator

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed by hand on December 23, 2020 with the Clerk's office and that the foregoing document will be served on the United States' attorneys, Kenneth G. Coffin, Esq. and Mary M. Cherry, Esq., by e-mail on December 23, 2020.

s/Steven Callahan
Steven Callahan